David Geffen School of Medicine

OCR Clinical Trials Contracts & Strategic Relations (CTC&SR)
Document Checklist for Clinical Trial Contract Review and Execution

		NEW CONTRACT	CONTRACT AMENDMENTS				
		A	B	C	D	E	F
		New Contract	Budget Increase: 1)Per Subject Costs (affects all subjects on trial) 2) Invoiceables 3)Fixed Costs 4) Increase # of subjects	Budget Decrease: 1) Per Subject Cost (remove item/service from ALL subjects OR 2) Invoiceables (e.g. remove set-up fee)	Change: PI SPONSOR CRO	NCTE: Amendment required if there is a firm fixed End Date in the Agreement	Miscellaneous Amendments that do not fall under categories B-E *(Documents/approvals TBD on case-by-case basis)*
		EMAIL ALL DOCUMENTS TO: clinicaltrials@mednet.ucla.edu (unless otherwise instructed)					
MINIMUM DOCUMENTS	**1) Pre-IRB or IRB NUMBER** ****(Document tracking will not begin until this step is completed.)*****:** • Email Notification confirming IRB # & Application • Application must include protocol, draft consent, & IB/device manual	☐					
	2) Sponsor/CRO Contact Information for Agreement/Amendment Negotiations: • Company name, contact name, email address, and phone number	☐	☐	☐	☐	☐	☐
	3) UCLA Form 700U for all Sponsors: • 700U **MUST** be fully completed. • Electronic, fully completed *draft* acceptable as Minimum Document; however, ORIGINAL 700U **MUST** be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7). click here for the form	☐	☐		☐		☐
	4) UCLA Form 700U Addendum for all Sponsors: • Electronic draft copy acceptable as Minimum Document; however, fully completed form **MUST** be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7). click here for the form	☐	☐		☐		☐
	5) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA: • 700U **MUST** be fully completed. • Electronic, fully completed *draft* acceptable as Minimum Document; however, ORIGINAL 700U **MUST** be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7). click here for the form	☐	☐		☐		☐
	6) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the CTA: • Electronic draft copy acceptable as Minimum Document; however, fully completed form MUST be submitted to CTC&SR (see FINAL DOCUMENTS section below). • For any positive disclosure - complete Industry CT Specific Supplement (see #7). click here for the form	☐	☐		☐		☐
	7) IF APPLICABLE - Industry CT Specific Supplement • For positive financial disclosure click here for the form	☐	☐		☐		☐
	8a) Draft Contract (Word document)	☐					
	8b) Draft Contract Amendment (Word document)		☐	☐	☐	☐	☐
FINAL DOCUMENTS	**9) UCLA Form 700U for all Sponsors:** • ORIGINAL WET-INK 700U **MUST** be fully completed, signed, and submitted to CTC&SR.	☐	☐		☐		☐
	10) UCLA Form 700U Addendum for all Sponsors: • **MUST** be fully completed, signed, and submitted to CTC&SR.	☐	☐		☐		☐
	11) IF APPLICABLE - UCLA Form 700U for CRO that signs the CTA: • ORIGINAL WET-INK 700U **MUST** be fully completed, signed, and submitted to CTC&SR.	☐	☐		☐		☐
	12) IF APPLICABLE - UCLA Form 700U Addendum for CRO that signs the CTA: • **MUST** be fully completed, signed, and submitted to CTC&SR.	☐	☐		☐		☐
	13) EPASS - Fully completed and signed. click here for EPASS	☐	☐		☐		☐
	14) PI Exception Letter • If applicable, contact your department for letter. click here for PI look up	☐			☐		☐
APPROVALS	**15) Conflict of Interest Review Committee (CIRC) Recommendation Letter -** *If item #7 required*	☐	☐		☐		☐
	16) IRB Approval *(To be verified in WebIRB/OnCore by CTC&SR Team)*	☐	☐	☐	☐	☐	☐
	17) Final Budget Signoff Email Notification *(Issued by OCR Research Quality (RQ))*	☐	☐	☐		☐	☐
	18) PI and CTC&SR Sign Final Agreement/Amendment	☐	☐	☐	☐	☐	☐